IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAIHO PHARMACEUTICAL CO., LTD. and TAIHO ONCOLOGY, INC., Plaintiffs, v. EUGIA PHARMA SPECIALITIES LTD., AUROBINDO PHARMA LTD., and AUROBINDO PHARMA U.S.A., INC., Defendants.	Civil Action No._____

COMPLAINT

Plaintiffs Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. (collectively, "Taiho" or "Plaintiffs"), for their Complaint for Patent Infringement and Declaratory Judgment against Defendants Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. (collectively, "Eugia" or "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Taiho Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-27 Kandanishiki-cho, Chiyoda-ku, Tokyo 101-8444, Japan.

2. Plaintiff Taiho Oncology, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 101 Carnegie Center, Suite 101, Princeton, New Jersey 08540.

3. Upon information and belief, defendant Eugia Pharma Specialities Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Plot #2, Maitrivihar, Ameerpet, Hyderabad 500038, Telangana, India.

4. Upon information and belief, defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Plot #2, Maitrivihar, Ameerpet, Hyderabad 500038, Telangana, India.

5. Upon information and belief, defendant Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

6. Upon information and belief, Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including the State of Delaware.

7. Upon information and belief, Aurobindo Pharma U.S.A., Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd. and is the United States agent for Eugia Pharma Specialities Ltd.

8. Upon information and belief, Eugia Pharma Specialities Ltd. is a subsidiary of Aurobindo Pharma Ltd.

9. Upon information and belief, Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. acted in concert to prepare and submit Eugia's Abbreviated New Drug Application ("ANDA") No. 213893 (trifluridine and tipiracil tablets) ("Eugia's ANDA Product") to the United States Food and Drug Administration ("FDA").

10. Upon information and belief, Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. are agents of each other and/or operate in concert as integrated parts of the same group, including with respect to Eugia's ANDA Product, and enter into agreements with each other that are nearer than arm's length.

11. Upon information and belief, Eugia Pharma Specialities Ltd. and Aurobindo Pharma Ltd. participated in, assisted, and cooperated with Aurobindo Pharma U.S.A., Inc. in the acts complained of herein.

12. Upon information and belief, following any FDA approval of Eugia's ANDA, Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. will act in concert to manufacture, market, distribute, and/or sell Eugia's ANDA Product throughout the United States, including within Delaware.

NATURE OF THE ACTION

13. This is a civil action for infringement of U.S. Patent Nos. RE46,284 E ("the '284 patent") and 10,138,223 B2 ("the '223 patent") (collectively, "the patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code § 100, *et seq.*, and in particular under U.S.C. § 271, as well as a civil action for declaratory judgment of patent infringement of the patents-in-suit under 28 U.S.C. §§ 2201-02. Taiho seeks declaratory relief, injunctive relief, attorneys' fees, and any other relief the Court deems just and proper.

14. This action relates to ANDA No. 213893, which Eugia filed or caused to be filed under 21 U.S.C. § 355(j) with the FDA, for approval to manufacture, use, and/or offer for sale a generic copy of Taiho's Lonsurf® (trifluridine and tipiracil) tablets throughout the United States prior to the expiration of the patents-in-suit.

JURISDICTION AND VENUE

15. This is a civil action for infringement arising under the United States Patent Laws, including 35 U.S.C. § 271, as well as a civil action for declaratory judgment of patent infringement under 28 U.S.C. §§ 2201-02.

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201-02.

17. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

18. This Court has personal jurisdiction over Eugia Pharma Specialities Ltd. because, *inter alia*, Eugia Pharma Specialities Ltd., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware; (3) has corporate affiliates that are organized under the laws of the State of Delaware; (4) maintains a broad distribution network within the State of Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

19. Upon information and belief, Eugia Pharma Specialities Ltd. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

20. Upon information and belief, Eugia Pharma Specialities Ltd. has substantial, continuous, and systematic contacts with the State of Delaware including Eugia Pharma Specialities Ltd.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

21. Upon information and belief, Eugia Pharma Specialities Ltd., and/or its subsidiaries, affiliates, or agents intends to engage in the commercial manufacture and sale of

Eugia's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

22. Upon information and belief, Eugia Pharma Specialities Ltd., and/or its subsidiaries, affiliates, or agents, intends to place Eugia's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

23. Upon information and belief, Eugia Pharma Specialities Ltd. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

24. Eugia Pharma Specialities Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, including by having asserted counterclaims in this jurisdiction in the matters, *inter alia*, of *Pfizer Inc. et al. v. Aurobindo Pharma, Ltd. et al.*, 19-cv-748 (D. Del.) and *Astellas Pharma Inc. v. Eugia Pharma Specialities Ltd. et al.*, 18-cv-757 (D. Del.).

25. Upon information and belief, Eugia Pharma Specialities Ltd. participated in the preparation, development, and filing of ANDA No. 213893, and its underlying subject matter, with the intent to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware. Taiho's causes of action arise from Eugia Pharma Specialities Ltd.'s contact with the State of Delaware.

26. Venue is proper in this Judicial District as to Eugia Pharma Specialties Ltd. because, *inter alia*, Eugia Pharma Specialities Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this Judicial District.

27. This Court has personal jurisdiction over Aurobindo Pharma Ltd. because, *inter alia*, Aurobindo Pharma Ltd., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware; (3) owns subsidiary companies that are organized under the laws of the State of Delaware; (4) maintains a broad distribution network within the State of Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

28. Upon information and belief, Aurobindo Pharma Ltd. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

29. Upon information and belief, Aurobindo Pharma Ltd. has substantial, continuous, and systematic contacts with the State of Delaware including Aurobindo Pharma Ltd.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

30. Upon information and belief, Aurobindo Pharma Ltd., and/or its subsidiaries, affiliates, or agents intends to engage in the commercial manufacture and sale of Eugia's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

31. Upon information and belief, Aurobindo Pharma Ltd., and/or its subsidiaries, affiliates, or agents, intends to place Eugia's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

32. Upon information and belief, Aurobindo Pharma Ltd. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

33. Aurobindo Pharma Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, including by having asserted counterclaims in this jurisdiction in the matters, *inter alia*, of *Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 19-cv-748 (D. Del.); *Genentech, Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 19-cv-103 (D. Del.); *Boehringer Ingelheim Pharma. Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 18-cv-1757 (D. Del.); *Kissei Pharma. Co. v. Aurobindo Pharma Ltd. et al.*, 17-cv-1161 (D. Del.); and *Amgen Inc. v. Aurobindo Pharma Ltd.*, 16-cv-853 (D. Del.).

34. Upon information and belief, Aurobindo Pharma Ltd. participated in the preparation, development, and filing of ANDA No. 213893, and its underlying subject matter, with the intent to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware. Taiho's causes of action arise from Aurobindo Pharma Ltd.'s contact with the State of Delaware.

35. Venue is proper in this Judicial District as to Aurobindo Pharma, Ltd. because, *inter alia*, Aurobindo Pharma, Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this Judicial District.

36. This Court has personal jurisdiction over Aurobindo Pharma U.S.A., Inc. because Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware. Aurobindo Pharma U.S.A., Inc. has a registered agent located at 251 Little Falls Drive, Wilmington, Delaware, 19808. This Court also has personal jurisdiction over Aurobindo Pharma U.S.A., Inc. because, *inter alia*, Aurobindo Pharma U.S.A., Inc., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware; (3) maintains a broad distribution network within the State of Delaware; and/or (4) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

37. Upon information and belief, Aurobindo Pharma U.S.A., Inc. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

38. Upon information and belief, Aurobindo Pharma U.S.A., Inc. has substantial, continuous, and systematic contacts with the State of Delaware including Aurobindo Pharma U.S.A., Inc.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

39. Upon information and belief, Aurobindo Pharma U.S.A., Inc., and/or its subsidiaries, affiliates, or agents intends to engage in the commercial manufacture and sale of Eugia's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

40. Upon information and belief, Aurobindo Pharma U.S.A., Inc., and/or its subsidiaries, affiliates, or agents, intends to place Eugia's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

41. Upon information and belief, Aurobindo Pharma U.S.A., Inc. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

42. Aurobindo Pharma U.S.A., Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, including by having asserted counterclaims in this jurisdiction in the matters, *inter alia*, of *Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 19-cv-748 (D. Del.); *Genentech, Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 19-cv-103 (D. Del.); *Boehringer Ingelheim Pharma. Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 18-cv-1757 (D. Del.); *Biogen Int'l GmbH et al. v. Aurobindo Pharma U.S.A., Inc.*, 17-cv-824 (D. Del.); and *Amgen Inc. v. Aurobindo Pharma Ltd.*, 16-cv-853 (D. Del.).

43. Upon information and belief, Aurobindo Pharma U.S.A., Inc. participated in the preparation, development, and filing of ANDA No. 213893, and its underlying subject matter, with the intent to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware. Taiho's causes of action arise from Aurobindo Pharma U.S.A., Inc.'s contact with the State of Delaware.

44. Venue is proper in this Judicial District as to Aurobindo Pharma U.S.A., Inc. because, *inter alia*, Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this Judicial District.

LONSURF®

45. Plaintiff Taiho Oncology, Inc. is the holder of the New Drug Application ("NDA") No. 207981 for the manufacture and sale of trifluridine and tipiracil tablets, 15mg and 20 mg, and sells the product in the United States under the registered trademark Lonsurf®.

46. The FDA approved NDA No. 207981 for the 15mg and 20mg tablets on September 22, 2015.

47. Plaintiff Taiho Oncology, Inc. sells and distributes Lonsurf® throughout the United States pursuant to NDA No. 207981.

48. Lonsurf® is indicated for the treatment of metastatic colorectal cancer that has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy as well as the treatment of metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. A copy of the February 22, 2019 Lonsurf® Label is attached as Exhibit A.

PATENTS-IN-SUIT

49. The '284 patent, entitled "Method of Administrating an Anticancer Drug Containing α,α,α-Trifluorothymidine and Thymidine Phosphorylase Inhibitor" was duly and legally reissued by the United States Patent and Trademark Office ("USPTO") on January 24, 2017. Taiho Pharmaceutical Co., Ltd. is the owner of all the right, title, and interest in and to the '284 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the '284 patent is attached as Exhibit B.

50. Pursuant to Federal Food, Drug, and Cosmetic Act ("FFD&C Act"), 21 U.S.C. § 355(b)(1) and corresponding FDA regulations, Taiho has submitted information concerning the

'284 patent to the FDA in connection with NDA No. 207981, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '284 patent has been listed in the FDA's Orange Book as covering Lonsurf® and methods for using it.

51. Claim 1 of the '284 patent is directed, *inter alia*, to a method for treating at least one of a digestive cancer and a breast cancer, comprising (i) orally administering a composition comprising α,α,α-trifluorothymidine ("FTD") and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ration of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer, (ii) wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area.

52. Claim 18 of the '284 patent is directed, *inter alia*, to a method for treating colorectal cancer comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m^2 is the human patient's body surface area

53. The approved Lonsurf® product labeling instructs medical personnel and/or patients to perform the steps of at least one claim of the '284 patent.

54. The use of Lonsurf® by patients and/or medical personnel in accordance with its approved product labeling by medical personnel and/or patients necessarily results in the performance of each step of at least one claim of the '284 patent.

55. The '223 patent, entitled "Stable Crystal Form of Tipiracil Hydrochloride and Crystallization Method for the Same" was duly and legally issued by the USPTO on November, 27 2018. Taiho Pharmaceutical Co., Ltd. is the owner of all the right, title, and interest in and to the '223 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the '223 patent is attached as Exhibit C.

56. Claim 1 of the '223 patent is directed, *inter alia*, to a polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2Θ ±0.2°) in powder X-ray diffraction.

EUGIA'S ANDA PRODUCT

57. Upon information and belief, pursuant to FFD&C Act, 21 U.S.C. § 355(j), Eugia submitted ANDA No. 213893 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eugia's ANDA Product within the United States prior to the expiration of the patents-in-suit.

58. Upon information and belief, Eugia's ANDA No. 213893 identified Taiho's Lonsurf® (trifluridine and tipiracil) tablets and included a written certification, as required by FFD&C Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the '284 patent and U.S. Patent No. 9,527,833 ("the '833 patent") are invalid or otherwise will not be infringed by Eugia's ANDA Product.

59. On or about November 8, 2019, Taiho received a letter from Eugia purporting to be a written notice that Eugia had filed ANDA No. 213893 seeking approval to market Eugia's ANDA Product prior to the expiration of the '284 patent, pursuant to FFD&C Act, 21 U.S.C. §

355(j)(2)(B) (the "Paragraph IV notice letter"). The Paragraph IV notice letter included notice of Eugia's allegations that the '284 patent is invalid and/or not infringed by Eugia's ANDA Product.

60. Eugia's submission of ANDA No. 213893, including the Paragraph IV certification, to the FDA constituted infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2).

61. Eugia's anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Eugia's ANDA Product upon approval of ANDA No. 213893 and before expiration of the patents-in-suit will infringe at least claims 1 and 18 of the '284 patent and at least claim 1 of the '223 patent under 35 U.S.C. § 271(a), (b), and/or (c).

62. Taiho commenced this action within 45 days of receiving Eugia's Paragraph IV notice letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. RE46,284

63. Paragraphs 1-62 are incorporated by reference as though fully set forth herein.

64. Administration of Taiho's Lonsurf® (trifluridine and tipiracil) tablets according to the Lonsurf® product labeling satisfies at least claims 1 and 18 of the '284 patent.

65. Upon information and belief, Eugia's ANDA Product has the same use as Lonsurf®, at least because Eugia's ANDA No. 213893 refers to and relies upon Taiho's NDA No. 207981 for Lonsurf®.

66. Upon information and belief, the proposed product labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

67. Upon information and belief, Eugia's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Lonsurf®.

68. Upon information and belief, Eugia's ANDA Product, or the use or manufacture thereof, is covered by at least claims 1 and 18 of the '284 patent.

69. Eugia's submission of ANDA No. 213893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Eugia's ANDA Product prior to the expiration of the '284 patent constitutes infringement of at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(e)(2).

70. Claim 1 of the '284 patent recites "A method for treating at least one of a digestive cancer and a breast cancer, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area."

71. Discovery will likely show that the product labeling for Eugia's ANDA Product will instruct medical personnel and/or patients to treat a digestive cancer by orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of a digestive cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area. Discovery will also likely show that the proposed labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

72. Claim 18 of the '284 patent recites "A method for treating colorectal cancer in a human patient, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m^2 is the human patient's body surface area."

73. Discovery will likely show that the product labeling for Eugia's ANDA Product will instruct medical personnel and/or patients to treat colorectal cancer in a human patient, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m^2 is the human patient's body surface area. Discovery will also likely show that the proposed labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

74. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Eugia's ANDA Product in the United States.

75. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '284 patent, with knowledge of said patent and said infringement.

76. Upon information and belief, the proposed product labeling for Eugia's ANDA will instruct medical personnel and/or patients to perform the steps of at least claims 1 and 18 of the '284 patent.

77. Upon information and belief, the use of Eugia's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claims 1 and 18 of the '284 patent.

78. Upon information and belief, Eugia specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Eugia knows infringe at least claims 1 and 18 of the '284 patent.

79. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(c) by selling or offering to sell Eugia's ANDA Product in the United States, with knowledge of the '284 patent and that there is no substantial non-infringing use of Eugia's ANDA Product.

80. Upon information and belief, Eugia knows that Eugia's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing at least claims 1 and 18 of the '284 patent.

81. Eugia's ANDA Product constitutes a material part of the invention covered by at least claims 1 and 18 of the '284 patent.

82. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 213893 shall be no earlier than the date on which the '284 patent expires, including any patent term and regulatory extensions.

83. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Taiho is entitled to a permanent injunction against further infringement. Taiho will be substantially and irreparably

harmed if Eugia's infringement of the '284 patent is not enjoined. Further, Taiho does not have an adequate remedy at law.

84. Upon information and belief, Eugia was aware of the '284 patent prior to Eugia submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without reasonable basis for a good faith belief that it would not be liable for infringing the '284 patent.

COUNT II – DECLARATORY JUDGMENT FOR INFRINGEMENT OF U.S. PATENT NO. RE46,284

85. Paragraphs 1-84 are incorporated by reference as though fully set forth herein.

86. Administration of Taiho's Lonsurf® (trifluridine and tipiracil) tablets according to the Lonsurf® product labeling satisfies at least claims 1 and 18 of the '284 patent.

87. Upon information and belief, Eugia's ANDA Product has the same use as Lonsurf®, at least because Eugia's ANDA No. 213893 refers to and relies upon Taiho's NDA No. 207981 for Lonsurf®.

88. Claim 1 of the '284 patent recites "A method for treating at least one of a digestive cancer and a breast cancer, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area."

89. Discovery will likely show that the product labeling for Eugia's ANDA Product will instruct medical personnel and/or patients to treat a digestive cancer by orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of a digestive cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area. Discovery will also likely show that the proposed labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

90. Claim 18 of the '284 patent recites "A method for treating colorectal cancer in a human patient, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m^2 is the human patient's body surface area."

91. Discovery will likely show that the product labeling for Eugia's ANDA Product will instruct medical personnel and/or patients to treat colorectal cancer in a human patient, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-

week dosing schedule wherein m^2 is the human patient's body surface area. Discovery will also likely show that the proposed labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

92. Upon information and belief, the proposed product labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

93. Upon information and belief, Eugia's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Lonsurf®.

94. Upon information and belief, Eugia's ANDA Product, or the use or manufacture thereof, is covered by at least claims 1 and 18 of the '284 patent.

95. Eugia's submission of ANDA No. 213893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Eugia's ANDA Product prior to the expiration of the '284 patent constitutes infringement of at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(e)(2).

96. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Eugia's ANDA Product in the United States.

97. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '284 patent, with knowledge of said patent and said infringement.

98. Upon information and belief, the proposed product labeling for Eugia's ANDA will instruct medical personnel and/or patients to perform the steps of at least claims 1 and 18 of the '284 patent.

99. Upon information and belief, the use of Eugia's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claims 1 and 18 of the '284 patent.

100. Upon information and belief, Eugia specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Eugia knows infringe at least claims 1 and 18 of the '284 patent.

101. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(c) by selling or offering to sell Eugia's ANDA Product in the United States, with knowledge of the '284 patent and that there is no substantial non-infringing use of Eugia's ANDA Product.

102. Upon information and belief, Eugia knows that Eugia's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing at least claims 1 and 18 of the '284 patent.

103. Upon information and belief, Eugia was aware of the '284 patent prior to Eugia submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95.

104. Upon information and belief, Eugia acted, and upon the FDA's approval of ANDA No. 213893, will act, without a reasonable basis for a good faith belief that it would not be liable for directly and indirectly infringing the '284 patent.

105. Pursuant to 28 U.S.C. § 2201, Taiho is entitled to a declaratory judgment that Eugia's making, using, offering to sell, selling and/or importing Eugia's ANDA Product, inducement therefor or contribution thereto, will infringe the '284 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

106. Pursuant to 28 U.S.C. § 2201 and 35 U.S.C. § 271(e)(4)(A), Taiho is entitled to a declaratory judgment that the effective date of any approval of ANDA No. 213893 shall be no earlier than the date on which the '284 patent expires, including any patent term and regulatory extensions.

107. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Eugia's ANDA Product with its proposed labeling, or any other Eugia drug that is covered by or whose use is covered by the '284 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '284 patent, and that the claims of the '284 patent are not invalid.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 10,138,223

108. Paragraphs 1-107 are incorporated by reference as though fully set forth herein.

109. Taiho's Lonsurf® (trifluridine and tipiracil) tablets meet every limitation of at least claim 1 of the '223 patent.

110. Upon information and belief, Eugia's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '223 patent.

111. Eugia's submission of ANDA No. 213893 seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Eugia's ANDA Product prior to the expiration of the '223 patent constitutes infringement of at least claim 1 of the '223 patent under 35 U.S.C. § 271(e)(2).

112. Claim 1 of the '223 patent recites "A polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ±0.2°) in powder X-ray diffraction."

113. Eugia's ANDA Product contains tipiracil HCl as one of its active ingredients. Discovery will likely show that Eugia's ANDA Product contains a polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ±0.2°) in powder X-ray diffraction.

114. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Eugia's ANDA Product in the United States.

115. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '223 patent, with knowledge of said patent and said infringement.

116. Upon information and belief, the use of Eugia's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '223 patent.

117. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(c) by selling and offering to sell Eugia's ANDA Product in the United States, with knowledge of the '223 patent and that there is no substantial non-infringing use of Eugia's ANDA Product.

118. Upon information and belief, Eugia knows that Eugia's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '223 patent.

119. Eugia's ANDA Product constitutes a material part of the invention covered by the claims of the '223 patent.

120. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Taiho is entitled to a permanent injunction against further infringement. Taiho will be substantially and irreparably harmed if Eugia's infringement of the '223 patent is not enjoined. Further, Taiho does not have an adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT FOR INFRINGEMENT OF U.S. PATENT NO. 10,138,223

121. Paragraphs 1-120 are incorporated by reference as though fully set forth herein.

122. Taiho's Lonsurf® (trifluridine and tipiracil) tablets meet every limitation of at least claim 1 of the '223 patent.

123. Upon information and belief, Eugia's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '223 patent.

124. Claim 1 of the '223 patent recites "A polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ±0.2°) in powder X-ray diffraction."

125. Eugia's ANDA Product contains tipiracil HCl as one of its active ingredients. Discovery will likely show that Eugia's ANDA Product contains a polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ±0.2°) in powder X-ray diffraction.

126. Eugia's submission of ANDA No. 213893 seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Eugia's ANDA Product prior to the expiration of the '223 patent constitutes infringement of at least claim 1 of the '223 patent under 35 U.S.C. § 271(e)(2).

127. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Eugia's ANDA Product in the United States.

128. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '223 patent, with knowledge of said patent and said infringement.

129. Upon information and belief, the use of Eugia's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '223 patent.

130. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(c) by selling and offering to sell Eugia's ANDA Product in the United States, with knowledge of the '223 patent and that there is no substantial non-infringing use of Eugia's ANDA Product.

131. Upon information and belief, Eugia knows that Eugia's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '223 patent.

132. Upon information and belief, Eugia acted, and upon the FDA's approval of ANDA No. 213893, will act, without a reasonable basis for a good faith belief that it would not be liable for directly and indirectly infringing the '223 patent.

133. Pursuant to 28 U.S.C. § 2201, Taiho is entitled to a declaratory judgment that Eugia's making, using, offering to sell, selling and/or importing Eugia's ANDA Product, inducement therefor or contribution thereto, will infringe the '223 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

134. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Eugia's ANDA Product with its proposed labeling, or any other Eugia drug that is covered by or whose use is covered by the '223 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '223 patent, and that the claims of the '223 patent are not invalid.

REQUEST FOR RELIEF

WHEREFORE, Taiho respectfully requests the following relief:

A. The entry of judgment on the Complaint in favor of Plaintiffs and against Defendants.

B. The entry of judgment that Eugia has infringed the '284 and '223 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 213893 to the FDA;

C. The entry of judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Eugia's ANDA Product before the expiration of the '284 and '223 patents including any patent term and regulatory extensions will constitute acts of infringement of the '284 and '223 patents by Eugia;

D. The issuance of an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 213893 shall be no earlier than the dates on which the '284 and '223 patents expire, including any patent term and regulatory extensions;

E. The issuance of an injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283, enjoining Eugia, its officers, agents, servants, employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active manufacture, use, sale, offer to sell, and/or importation within the United States, of any pharmaceutical product covered by the '284 and '223 patents prior to the expiration of said patents including any patent term and regulatory extensions;

F. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C) and/or 35 U.S.C. § 284 as appropriate;

G. A finding that this is an exceptional case under 35 U.S.C. § 285, and an award to Taiho of its reasonable attorneys' fees and costs; and

H. An award of any such other and further relief as the Court may deem just and proper.

ASHBY & GEDDES

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